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EXAMINER

HUNT, J

ART UNIT	PAPER NUMBER
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1642

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DATE MAILED: 08/15/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.
09/340,196

Applicant(s)
Kato et al.

Examiner
Jennifer Nichols, Nee Hunt

Group Art Unit
1642



☒ Responsive to communication(s) filed on May 23, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 4, 10, 11, 15, 16, and 19-29 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 4, 10, 11, 15, 16, and 19-29 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 7,8

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Response to Amendment

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Acknowledgment is made of applicant's cancellation of claims 1-3, 5-9, 12-14, and 17-18. Claims 4, 10-11, 15-16, and 19-29 are pending in the application.

Claim Rejections Withdrawn

1. All rejections of claims 1-3, 5-9, 12-14, and 17-18 are withdrawn in light of the cancellation thereof.

Claim Rejections Maintained

2. The rejections of claims 4, 10, 11, 15, 16, under 35 USC 112 2nd paragraph as being unclear in the recitation of "a sample originating from a living body" is maintained and applied to new claims 19-23, and 26-29 for reasons of record in the Office Action of January 21, 2000. Applicant has neither amended the claims, nor presented arguments to overcome the rejection.

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The metes and bounds of a sample originating from a living body cannot be determined. It is not clear what would be considered a sample originating from a living body and what would not.

3. The rejections of claims 4, 10, 11, 15, 16, under 35 USC 112 2nd paragraph as being unclear in the recitation of “a specific thyroglobulin”, “specific sugar chain” “specific lectin” or “specific antibody” is maintained and applied to new claims, 19-28 for reasons of record in the Office Action of January 21, 2000. Applicant has neither amended the claims, nor presented arguments to overcome the rejection. The metes and bounds of “a specific thyroglobulin”, “specific sugar chain” “specific lectin” or “specific antibody” cannot be determined. It is not clear what would be considered a “a specific thyroglobulin”, “specific sugar chain” “specific lectin” or “specific antibody” and what would not.

4. The rejections of claims 4, 10, 11, 15, 16, under 35 USC 112 2nd paragraph as being unclear in the recitation of “a sugar chain other than the specific sugar chain”, is maintained and applied to new claims 19-29. Applicant has neither amended the claims, nor presented arguments to overcome the rejection. The metes and bounds of “a sugar chain other than the specific sugar chain” cannot be determined. It is not clear what would be encompassed by a “a sugar chain other than the specific sugar chain” and what would not.

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5. Claims 4, 10-11, and 15-16 stand rejected under 35 USC 102(a). Newly added claims 19-25, and 27-28 are also rejected under 35 U.S.C. 102(a) as being anticipated by Maruyama et al., Arch. Pathol Lab Med, Vol 122, August 1998, for reasons of record, set forth in the Office Action of January 21, 2000, and reiterated below for clarity.

Maruyama et al. teaches a method of measuring thyroglobulin and detecting malignancy from a sample from a living body by using proteins which bind to a constant region and lectins which bind a specific sugar chain structure, where the specific sugar chains are D-galactose, D-mannose, or N-acetyl-D-galactosamine. The specific lectins Concanavalin a, *Ricinus communis*, and *lens culinaris* agglutinin are taught.(page 716, 1st paragraph). Maruyama et al. also teaches the specific reagent of the method, separation of the thyroglobulin, and the specific determination of thyroid carcinoma.(see abstract)

Applicant's arguments filed May 23, 2000 have been fully considered but they are not persuasive. Applicant argues that this reference was published after the priority date (June 30, 1998) of the application for which priority is claimed.

This argument is not found to be persuasive because, as set forth in the previous Office Action, applicant cannot rely upon the foreign priority papers to overcome these rejections because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15. a certified translation of the priority document is not of record in this case. Thus the priority is not granted, and the rejection of claims 1-18 over Maruyama et al. is maintained.

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6. Newly added claims 19, 21, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by SAR van de Graaf et al, European Journal of Endocrinology, 1997 for reasons of record, set forth in the Office Action of January 21, 200, and reiterated below for clarity.

SAR van de Graaf et al. teaches a method of measuring thyroglobulin from a sample from a living body, the sample containing a specific thyroglobulin, which is a thyroglobulin having a specific sugar chain to which a specific lectin or specific antibody is capable of binding, other thyroglobulin having a sugar structure other than the specific sugar structure to which said specific lectin or specific antibody binds and other ingredients, comprising using an anti-thyroglobulin antibody which bind to a constant region and lectins which bind a specific sugar chain structure, and determining the other thyroglobulin from the differences between. (Page 512, 2nd paragraph)

Applicant's arguments filed May 23, 2000 have been fully considered but they are not persuasive. Applicant argues that (1) the reference discloses isolation of thyroglobulin using lectins only, that (2) there is no disclosure of the measurement of the amount of Tg, and that (3) the reference does not disclose determination of malignancy. This argument is not found to be persuasive because (1) The reference clearly states that TG proteins were immunoprecipitated and total TG isolated using RaHuTG, which is an anti-thyroglobulin antibody. (2) These isolated thyroglobulins were then analyzed and detected with 4 different lectins, and (3) the claims this reference is applied to do not recite the limitation for determination of malignancy or tumor.

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Applicant's arguments are not commensurate in scope with the invention recited in the claims, as the claims do not recite a limitation of determining malignancy or a tumor.

7. Claims 4, 10-11, 15-16, stand rejected under 35 USC 102(b). Newly added claims 19-25, and 27-28 are also rejected under 35 U.S.C. 102(b) as being anticipated by Hanham et al. Biochemica et Biophysica Acta, Vol 884, 1986 for reasons of record, set forth in the Office Action of January 21, 200, and reiterated below for clarity.

Hanham et al. teaches a method of measuring thyroglobulin from a sample and detecting malignancy from a sample from a living body, the sample containing a specific thyroglobulin, which is a thyroglobulin having a specific sugar chain to which a specific lectin or specific antibody is capable of binding, other thyroglobulin having a sugar structure other than the specific sugar structure to which said specific lectin or specific antibody binds and other ingredients, comprising using an anti-thyroglobulin antibody which bind to a constant region and lectins which bind a specific sugar chain structure, and determining the other thyroglobulin from the differences between, where the specific sugar chains are D-galactose, D-mannose. The specific lectins Concanavalin a, *Ricinus communis*, and are taught. (see abstract, page 158, 2nd paragraph, and 164 whole page). Hanham et al. also teaches the specific reagent of the method, separation of the thyroglobulin, and the specific determination of thyroid carcinoma. (page 158, 2nd paragraph)

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Applicant's arguments filed May 23, 2000 have been fully considered but they are not persuasive. Applicant argues that (1) the reference discloses isolation of thyroglobulin using lectins only, that (2) there is no disclosure of the measurement of the amount of Tg, and that (3) the reference does not disclose determination of malignancy. This argument is not found to be persuasive because (1) The reference clearly states that an anti-thyroglobulin antibody was used as part for the measurement (page 163, column 2). (2) These isolated thyroglobulins were "quantified" (see, for example, abstract and figures 1-6), and (3) These determinations are useful for determining thyroid disease, including thyroid malignancy (page 158, abstract and column 2).

8. Claims 4, 10-11, 15-16 stand rejected under 35 USC 102(b). Newly added claims 19-25, and 27-28 are also rejected under 35 U.S.C. 102(b) as being anticipated by Tarutani et al, Journal of Biochemistry, Vol 98, pages 851-857, 1985 for reasons of record, set forth in the Office Action of January 21, 2000, and reiterated below for clarity.

Tarutani et al. teaches a method of measuring thyroglobulin from a sample and detecting malignancy from a sample from a living body, the sample containing a specific thyroglobulin, which is a thyroglobulin having a specific sugar chain to which a specific lectin or specific antibody is capable of binding, other thyroglobulin having a sugar structure other than the specific sugar structure to which said specific lectin or specific antibody binds and other ingredients, comprising using an anti-thyroglobulin antibody which bind to a constant region and

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lectins which bind a specific sugar chain structure, and determining the other thyroglobulin from the differences between, including Concanavalin a. Tarutani et al also teaches the specific reagent of the method, separation of the thyroglobulin, and the specific determination of thyroid carcinoma via comparison of total thyroglobulin lectin binding and modified thyroglobulin lectin specificity.(see abstract)

Applicant's arguments filed May 23, 2000 have been fully considered but they are not persuasive. Applicant argues that (1) the reference discloses isolation of thyroglobulin using lectins only, that (2) there is no disclosure of the measurement of the amount of Tg, and that (3)the reference does not disclose determination of malignancy. This argument is not found to be persuasive because (1) The reference clearly states that an anti-thyroglobulin antibody was used as part for the measurement (page 854, column 1). (2) These isolated thyroglobulins were "quantified" (see, for example, Tables I and II), and (3) These determinations are useful for determining thyroid disease, including thyroid malignancy (see for example, Tables I and II).

9. Claims 10-11, 15-16, stand rejected under 35 USC 102(b). And newly added claims 19-22, 24-25, and, 27-28 are also rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al., Chung-hua Ping Li Hsueh Tsa Chin, Volume 19, No 2, pages 90-93 for reasons of record, set forth in the Office Action of January 21, 200, and reiterated below for clarity.

Wang teaches of measuring thyroglobulin from a sample and detecting malignancy from a sample from a living body, the sample containing a specific thyroglobulin, which is a

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thyroglobulin having a specific sugar chain to which a specific lectin or specific antibody is capable of binding, other thyroglobulin having a sugar structure other than the specific sugar structure to which said specific lectin or specific antibody binds and other ingredients, comprising using an anti-thyroglobulin antibody which bind to a constant region and lectins which bind a specific sugar chain structure, and determining the other thyroglobulin from the differences between. Wang et al also teaches the specific reagent of the method, separation of the thyroglobulin, and the specific determination of thyroid carcinoma.(see abstract).

Applicant's arguments filed May 23, 2000 have been fully considered but they are not persuasive. Applicant argues that (1) the reference discloses isolation of thyroglobulin using lectins only, that (2) there is no disclosure of the measurement of the amount of Tg, and that (3)the reference does not disclose determination of malignancy. This argument is not found to be persuasive because (1) The reference teaches immunohistochemical detection, and use of an anti-thyroglobulin antibody for detection of thyroglobulin is an art standard from of immunohistochemical detection as set forth in the references above.. (2) These isolated thyroglobulins were “quantified”, and (3) These determinations are useful for determining thyroid disease, including thyroid malignancy.(see abstract).

New Grounds of Rejection

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10. Claims 4, 10, 11, 15, 16, 19-23, and 26-29 are now unclear in the recitation of “other ingredients”. The metes and bounds of other ingredients cannot be determined. It is not clear what would be encompassed by other ingredients and what would not.

11. Claims 4, 19, 23, and 26 are now unclear in the recitation of “contained in the sample”. It cannot be determined what is being referred to, therefore it is unclear what is contained in the sample and what is not.

12. Claims 4, 19, 23, and 25-26 provide for the use of an anti-thyroglobulin antibody, and a lectin, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 4, 19, 23, and 25-26 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

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13. Claims 4, 20, 22- 26, and 28-29 are now incomplete because they omit essential steps. See MPEP § 2172.01. While all of the technical details of the method need not be recited, the claims should include enough information to clearly and accurately describe the invention and how it is practiced.

The minimum requirement for method steps should at least include a contacting step in which the reaction of the sample with the reagents necessary for the assay is recited, a detection step in which the reaction steps are quantified or visualized and a correlation step describing how the results of the assay allow the determination. In the instant case, the claims fail to recite a correlation step, for example, correlating how the amount of thyroglobulins corresponds to thyroid malignancy. Although the claims recite determining a difference between the two thyroglobulin measurements to determine malignancy, the claims fail to set forth what difference would be indicative of malignancy and what difference would not. Furthermore, claims 20-21 fail to recite a contacting step.

14. Claim 4, 23, 26, and 29 are improper because they depend from multiple claims, but fail to refer to claims in alternative form. For example, amending the claims to recite --19, 20, 21, or 22-- will obviate this rejection.

15. Claim 19 is unclear in the recitation of “amounts”. The use of the plural term “amounts” with the singular object, “thyroglobulin” makes it unclear what other amount is encompassed.

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16. Claim 25 is unclear in the recitation “anti-thyroglobulin”. It is not clear if this refers to the anti-thyroglobulin antibody, or if this recitation represents a new structure.

17. Claim 27, step (b) is unclear in the recitation of determined. The preamble of the claim recites “measuring” but the correlation recites “determined”. These terms are not equivalent, and thus it is not clear that the correlation step refers back to the preamble. Applicant is requested to use the same term throughout the claim.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) a patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. Claims 4, 10-11, 15-16, and 19-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maruyama et al., SAR van de Graaf et al, Hanham et al., Tarutani et al, or Wang et al. in view of Larena, a et al., Langenbecks Archiv fur Chirurgie Vol 381/2 pages 102-113 1996.

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Maruyama et al., SAR van de Graaf et al, Hanham et al., Tarutani et al, or Wang et al. Teach as set forth above and applied to claims 4, 10-11, 15-16, 19-25, and 27-28 supra. Maruyama et al., SAR van de Graaf et al, Hanham et al., Tarutani et al, or Wang et al. fail to teach an anti-thyroglobulin antibody reactive with a Lewis type sugar chain.

Larena et al. teaches that Lewis type sugar chains are known in the art to be useful for detection of malignancy, including thyroid malignancy. Larena compares levels to total thyroglobulin to Lewis expressing thyroglobulin as well as normal thyroid tissue to cancerous tissue.

Therefor it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the antibody of Larena et al. as the anti-thyroglobulin antibody in the methods of any of Maruyama et al., SAR van de Graaf et al, Hanham et al., Tarutani et al, or Wang et al. because the antibody is detectable in normal and cancerous tissue and useful for determination of thyroid malignancy as set forth in Larena et al.

No claims are allowed.

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Nichols, whose telephone number is (703) 308-7548. The examiner can normally be reached Monday through Thursday 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached at (703) 308-3995. The fax number for the group is (703) 305-3014 or (703) 308-4242.

Communications via internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [anthony.caputa@uspto.gov].

All internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists the possibility that

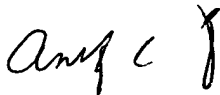
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sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist, whose telephone number is (703) 308-0196.

Jennifer Nichols, Nee Hunt

August 14, 2000


ANTHONY C. CAPUTA
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